

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEM,  
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

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THIS DOCUMENT RELATES TO ALL CASES

**NOTICE TO TAKE ORAL DEPOSITION  
OF DEFENDANT THROUGH DESIGNATED WITNESS, SUSAN LIN**

TO: Defendant ETHICON, INC., and Johnson & Johnson, Inc., (hereinafter “Defendants”)  
and its Attorneys of Record.

Please take notice that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants’ corporate designee SUSAN LIN on March 12 and March 13, 2013, at 9:00 a.m., at an agreed upon location. The witness shall be prepared to testify concerning the subject matters identified in Exhibit “A”, attached hereto. The witness shall produce documents identified in Exhibit “B”, attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

**DEFINITIONS**

All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. “Concerning” or “Concern” means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).

2. “Relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” or “reflect,” shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in preparation of or concerning the preparation of the documents.

3. “Defendants”, “Ethicon”, “Ethicon, Inc.”, “Johnson & Johnson Inc.”, “you” or “your” refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

4. “You” and “your” mean Defendants and any of its directors, officers, sales representatives, agents (including attorneys, accountants, consultants, investment advisors or bankers), employees, representatives and any other person purporting to act on its behalf. In the case of business entities, these defined terms include divisions, affiliates, subsidiaries, predecessor entities, acquired entities, related entities, or any other entity acting or purporting to act on your behalf.

5. “Document” or “Documents” is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

6. “TVT” or “TVT products” means the TVT “classic” Tension Free Vaginal Tape System, as well as the TVT-Obturator, TVT-Secur, TVT-Exact, and TVT-Abbrevio which were developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI). The term “TVT” or “TVT products” also includes any kits or tools designed to be sold with the TVT products including, but not limited to the TVT-AA and TVT-D.

7. “Or” and “and” will be used interchangeably, and should be construed so as to give any definition or subject matter the broadest possible meaning.

8. “Relevant Time Period” means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT to the present.

9. You are to produce all responsive documents to the undersigned counsel no later than 10 days before the deposition.

**PLAINTIFFS’ CO-LEAD COUNSEL**

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**EXHIBIT "A"**

**DEPOSITION SUBJECT MATTER**

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

**IV. REGULATORY AFFAIRS RELATED TO THE TVT PRODUCTS**

1. The corporate organization charts and structure of all Ethicon, Inc. employees relating to the TVT products from the date Ethicon, Inc. first started developing TVT until the present.

2. The approval, management, administration, operation and compliance with any and all U.S. medical device regulations applicable to your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

3. The approval, management, administration, operation and compliance with any and all foreign medical device regulations applicable to your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

4. The person(s) or entities (including but not limited to their titles, duties and dates of such responsibility) who was or is responsible for communicating with regulatory officials with the FDA and related regulatory bodies concerning regulatory approval and compliance with U.S. medical device regulations concerning your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

5. The person(s) or entities (including but not limited to their titles, duties and dates of such responsibility) who was or is responsible for communicating with foreign regulatory bodies about your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

6. Ethicon, Inc.'s practices and procedures for the review, submission and approval concerning its TVT products relating to the following regulatory provisions:

- a. Labeling, contraindications and adverse event warnings;
- b. Post-marketing reporting and warnings;
- c. Adverse event evaluations, assessments, reporting, databases, or other expertise related to adverse events;
- d. The intake, investigation, processing, handling and reporting to the FDA and other governmental regulatory bodies of all adverse event reports;
- e. Tracking, recording, reporting, handling, following up on complaints, problems, and adverse event reports relating to your TVT products;
- f. 510(k) compliance, submission, preparation, decision making or any other issues related to 510(k) compliance or submission.

7. The location, storage and organization of any and all documents that relate to U.S. and foreign regulatory affairs and matters concerning Ethicon, Inc.'s TVT products, including but not limited to:

- a. regulatory communications;
- b. interchanges between Ethicon, Inc.'s personnel and any regulatory body or personnel;
- c. memoranda;
- d. electronic data;
- e. working drafts;
- f. regulatory guidance documents;
- g. internal writings;
- h. communications to and from Ethicon, Inc. personnel regarding regulatory matters;
- i. labeling records, including drafts of labeling records;

- j. minutes of meetings with regulatory personnel;
- k. regulatory contact reports or sheets;
- l. Investigational device submissions;
- m. 510(k) submissions;
- n. Safety Update Reports; and
- o. Any and all other documents which in any way relate to regulatory affairs applicable to your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

8. Communications between Ethicon, Inc. and the FDA regarding the marketing, sale, promotion or advertising of TVT products.

9. Communications between Ethicon, Inc. and the FDA concerning the review, analysis and summaries of post-marketing adverse event reports regarding its TVT products.

10. The processes and procedures used by Ethicon, Inc. in connection with processing TVT related adverse event reports, including the identification of policy manuals, SOPs, and safety or pharmacovigilance manuals.

11. The procedures for the intake, processing, handling, analyzing, investigating and reporting to the FDA and to any other U.S. governmental bodies reports of adverse events concerning your TVT products.

12. The processes and procedures by which Ethicon, Inc. receives and processes clinical trial adverse events from its clinical trials, including the processes by which Ethicon, Inc. conducts follow-up investigations on adverse event reports from its clinical trials or post marketing surveillance.

13. The processes and procedures by which a determination is made by Ethicon, Inc. as to whether an adverse event should or should not be found to be related to one of its TVT products.

14. The identity of all databases that contain adverse event reports from any source.

15. The existence, maintenance, and location of records of all contacts with the FDA or communications between Ethicon, Inc. and the FDA related to adverse event reports, adverse event reporting, pharmacovigilance, or postmarketing surveillance concerning the TVT products.

16. The process and procedures for storing, testing and/or analyzing TVT products that have been returned to Ethicon, Inc. due to complaints of malfunction or complications and the location of any and all such storage facilities.

17. The date each patient brochure related to the TVT products received any and all approvals (both within Ethicon, Inc. and by the FDA or other regulatory agency) necessary to make such changes.

18. Any changes to draft TVT patient brochures requested by the FDA.

## **EXHIBIT “B”**

### **DOCUMENT REQUESTS**

From any electronic or physical files kept, maintained, controlled or accessible by Susan Lin or the Defendants, please produce the following:

1. All documents relied upon by the deponent in preparing for this deposition.
2. All documents concerning corporate, departmental, and employee organizational charts.
3. A copy of the current resume and/or curriculum vitae for Susan Lin
4. A copy of the personnel file and/or employment file for Susan Lin

5. All documents, notes, videos, or other information relating to TVT products that Susan Lin sponsored, supported, edited, posted, and/or linked websites, FaceBook pages, MySpace pages, Twitter pages, Wikipedia, or pages on any other websites.

6. All documents concerning your protocol or standard operating procedures (SOP) for Ethicon, Inc.'s regulatory department.

7. All draft and final package inserts, product labels, and instructions for use created for any TVT products.

8. All documents that index or catalog Defendants' approved or draft advertising, sales and marketing materials, and print and broadcast advertisements, sales aids, visuals, sales scripts, sales guides, and reminder pieces relating to TVT products.

9. All documents relating to, submitted to, created by, or concerning any committee or group that reviews and approves any labeling, packaging, advertising, sales and marketing materials, or external communications relating to TVT products.

10. Documents sufficient to identify all countries in which the TVT products have been cleared and/or approved for sale and the date on which each was cleared and/or approved.

11. All documents relating to any FDA 522 Orders for TVT products.

12. All documents relating to Ethicon's decision to cease commercialization of or withdraw from market any TVT products.

13. All documents concerning any governmental agency in any country worldwide that declined to clear and/or approve an application to market the TVT products or for any indication, including, but not limited to, communications between the sponsor of the TVT products and the agency, and any English translations that exist if the Documents are written in any language other than English.



14. All documents that concern, or involve discussion about, the potential or actual submission of TVT products for clearance and/or the approval of TVT in another country besides the U.S. including, but not limited to, communications regarding foreign governmental agencies and their drug approval procedures, rules and/or standards, and including any English translations that exist if the documents are written in any language other than English.

15. All documents concerning deferred approval of TVT products in any country, including any English translations that exist if the documents are written in any language other than English.

16. All documents that relate to U.S. and foreign regulatory affairs and matters concerning Ethicon, Inc.'s TVT products, including but not limited to regulatory communications, interchanges between Ethicon, Inc.'s personnel and any regulatory body or personnel, memoranda, electronic data, working drafts, regulatory guidance documents, internal writings, communications to and from Ethicon, Inc. personnel regarding regulatory matters, labeling records, drafts of labeling records, minutes of meetings with regulatory personnel, regulatory contact reports or sheets, Investigational device submissions, 510(k) submissions, Safety Update Reports, and any and all other documents which in any way relate to regulatory affairs applicable to your TVT products from the date Ethicon, Inc. first started developing TVT until the present.